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10/698,031	10/29/2003	Brian Mann	SAVCOR.1C2CP1	1212

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EXAMINER	
LAYNO, CARL HERNANDZ	

ART UNIT	PAPER NUMBER
3766	

NOTIFICATION DATE	DELIVERY MODE
07/11/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/698,031	MANN ET AL.	
	Examiner	Art Unit	
	Carl H. Layno	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-146* is/are pending in the application.

4a) Of the above claim(s) *102-118 and 126-145* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☒ Claim(s) *See Continuation Sheet* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 October 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims rejected are 1-3,5,7,8,10,11,14-18,24-27,30,31,37,41-47,49,50,53,57,59-66,68,69,74,75,77-79,82,87-93,97,119,122-125 and 146.
Continuation of Disposition of Claims: Claims objected to are 4,6,9,12,13,19-23,28,29,32-36,38-40,48,51,52,54-56,58,67,70-73,76,80,81,83-86,94-96,98-101,120 and 121.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :4/24/06,4/21/06,12/7/05,11/29/05,4/4/05,4/9/04.

DETAILED ACTION

Election/Restrictions

1. Claims 102-118 and 126-145 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 7, 2007. The requirement is therefore made FINAL.

2. Claims 1-101, 119-125, and 146 are active.

Specification

3. The disclosure is objected to because of the following informalities:

- p.2 of the specification, line 2, should be updated to reflect the fact that US Application No. 10/127,227 is now US Patent No. 7,115,095, and
- p.2, of the specification, line 7, should be updated to reflect the fact that US Application No. 10/697,960 is now US Patent No. 6,970,742.

Appropriate correction is required.

Information Disclosure Statement

4. Acknowledgment is made of applicant's Information Disclosure Statements (PTO-1449s), which were received by the Office on 4/24/2006, 4/21/2006, 12/7/2005, 11/29/2005, 4/4/2005, and 4/9/2004.

"Applicant should note that the large number of references in the attached IDS' have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. **See MPEP 609.05(b).** Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action."

Drawings

5. The drawings are objected to because the numbering and labels of Figs.25, 26A, 26B, 28, and 29 are informal. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

6. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

As written, Applicant's present Abstract is over 170 words.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 5 recites the limitation "the external patient advisory module" in line 1. There is insufficient antecedent basis for this limitation in the claim. To overcome this rejection, the Examiner recommends changing the claim dependency to depend from claim 4.

9. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the statement "the pressure signal comprises a central venous blood pressure or a peripheral arterial blood pressure" is confusing in that it contradicts the statement of claim 1 that the sensor is "indicative of fluid pressure within a left atrium".

10. Claims 89, 90, 124, and 125 recite the limitation "said implantable flexible lead" in line 1. There is insufficient antecedent basis for this limitation in the claim. To overcome these

rejections, the Examiner recommends changing the words "at least one implantable lead" in independent base claims 1 and 119 to "at least one implantable flexible lead".

11. Claim 122 recites the limitation "the external patient advisory module" in line 1. There is insufficient antecedent basis for this limitation in the claim. To overcome this rejection, the Examiner recommends changing the claim dependency to depend from claim 121.

12. Claim 123 similarly recites the limitation "the patient advisory module" in line 1. There is insufficient antecedent basis for this limitation in the claim. To overcome this rejection, the Examiner recommends changing the claim dependency to depend from claim 121.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the

reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

14. Claims 1-3, 7, 8, 10, 11, 14, 16, 24-27, 30, 31, 37, 41, 43, 44, 53, 57, 59, 61-65, 68, 69, 74, 75, 77, 78, 87, 88, 91-93, 97, and 146 are rejected under 35 U.S.C. 102(b) as being anticipated by Cohen (US 5,163,429).

In regard to claims 1-3, 7, 8, 10, 14, 16, 26, 27, 44, 59, 65, 68, 69, 87, 91-93, and 146, the Cohen (US 5,163,429) patent describes an implantable system (Fig.1) equipped with a lead/cable **19** (Fig.2E) having a distally located pressure transducer/sensor **20** for sensing pressure in the patient's left atrium **28**. The implantable rhythm management device (Fig.10) of Cohen includes anti-tachycardia and anti-bradycardia pacing circuits **86,97** as well as cardioversion/defibrillation circuits **65,66,73,74** for delivering at least two kinds of treatment signals to a patient. The implantable rhythm management device also includes a microprocessor **93** for performing the function of applicant's "signal processor". Microprocessor 93 processes pressure sensor signals from inputs **41,42** and from these derives appropriate output stimulation signals. The Examiner is taking the position that the patient would be able to distinguish the activation of a defibrillation pulse from any other treatment signal since it would be painfully felt as a noticeable jolt.

In regard to claim 11, the pressure transducer/sensor **20** may alternatively be located in the left ventricle (Fig.2D), right ventricle (Fig.2A), right atrium (Fig.2B), pulmonary artery (Fig.2H), pulmonary vein, or pulmonary capillary wedge pressure (col.9, lines 50-52).

In regard to claim 24, the therapy signals generated by the Cohen device may be delivered to a patient during three minute time intervals (col.14, lines 55-59).

In regards to claim 25, the sensor signal is sampled in response to the detection of an accelerated heart rate (top three blocks of Fig.7A).

In regard to claim 27, the transducer/sensor **20**, as shown in Figs.2A-2H, appears to be drawn as a short cylinder.

In regard to claim 30, applicant's attention is directed to lead/cable **19** (Figs.2A-2H) to which the pressure transducer/sensor **20** is attached.

In regard to claim 31, cable **19** comprises leads **19a** and **19b** (Fig.2E).

In regard to claims 37 and 97, in addition to pressure transducer/sensor **20**, the Cohen device is equipped with ECG rate sensors **18** (Fig.1).

In regard to claim 41, the implantable device of Cohen, as shown in Fig.1, appears to be resident within the patient's abdomen.

In regard to claim 43, the Cohen device includes a battery **64** (Fig.10).

In regard to claim 53, the Cohen device includes memory in the form of RAM **95** (Fig.10) and ROM **94**.

In regard to claim 57, detected pressure is used to detect hemodynamic compromise. If compromise is detected, the device may generate a cardioversion or defibrillation pulse. See flowcharts of Figs. 16A, 18A, and 20A.

In regard to claims 61-64, the Cohen device includes pacemaker lead **23** (Figs.2A-2J) and defibrillator lead **15** (Figs.2A-2J) both of which carry electrical "lead" signals.

In regard to claims 74 and 75, the device of Cohen performs the function of an automatic "cardiac rhythm management device" since the device executes pre-programmed algorithms with no user intervention.

In regard to claims 77 and 78, the therapy device of Cohen would inherently react to high blood pressure (i.e. an indication of CHF) and to high heart rates indicative of fibrillation (atrial or ventricular).

In regard to claim 88, the Cohen device is used to treat any and all patients suffering from a malfunctioning heart. This would inherently include those having CHF.

15. Claims 1-3, 7, 11, 14, 17, 18, 25, 26, 30, 31, 37, 42-47, 49, 50, 53, 57, 59-64, 66, 68, 69, 79, 82, 87, 88, 91-93, 97, 119, and 146 are rejected under 35 U.S.C. 102(e) as being anticipated by Struble (US 6,580,946).

In regard to claims 1-3, 11, 14, 30, 44, 59, 68, 69, 87, 91, 92, and 146, the Struble (US 6,580,946) patent describes an implantable cardiac pacing/defibrillating system (Fig. 6) comprising a pressure sensor **106** attached by lead **104** to a pressure monitor **102**, which detects average left atrium pressure (LAP) indirectly by first detecting pressure in the right ventricle that causes the pulmonary valve to open. The Struble system includes an implantable rate responsive cardiac pacemaker/defibrillator **114** (Fig.6) having a plurality of pacing leads **116,120** with associated electrodes **118,122**, and a defibrillation lead **124** with electrode **126**. A signal processor **110** generates modifications to pacing/defibrillating outputs based upon input signals from the pressure monitor **102**. The cardiac pacemaker/defibrillator **114** (Fig.5) includes a shock circuit **33,35,69,27** and pacing generators **65,67**, which perform the function of applicant's claimed "signaling device" because the pain associated with a defibrillation shock would be an indication to the patient that defibrillation is underway. This is distinguishable from the delivery of pacing therapy, which causes no discomfort.

In regard to claim 7, the pressure sensor **106** can be a piezoresistive pressure transducer (col.12, lines 47-49).

In regard to claims 17 and 18, the pressure signal sensed is a "parameter of left atrial pressure" (i.e. the mean or average left atrium pressure (LAP)).

In regard to claim 25, pressure is sensed in response to the detection of a heart valve opening.

In regard to claim 26, the pressure monitor **102** (Fig.6) performs the function of the "sensor module".

In regard to claim 31, Fig.6 shows that pressure/sensor module **114** is connected to the implantable housing **114** via what appears to be a wire connection **134** for communicating ECG information.

In regard to claims 33 and 93, the "sensor module" **102** (Fig.6) would inherently have electronics to receive and analyze pressure signals before sending pressure data **108** to processor **110** (col.12, lines 37-38).

In regard to claim 37, the Struble cardiac pacemaker/defibrillator **114** (shown in Fig.5) includes additional sensors **37** and **43** for detecting atrial and ventricular ECGs.

In regard to claims 42, 45, and 46, the Struble pacemaker/defibrillator is equipped with an antenna **56** (Fig.3) for wireless telemetry.

In regard to claim 43, the Struble pacemaker/defibrillator is equipped with a battery **76** (Fig.3).

In regard to claims 47, 49, 50, 60, 79, and 82, externally located I/O devices **128** (Fig.6) and RF telemetry module **130** can perform the function of the "signal processor" by permitting a

physician to "exchange information with processor **110**, pressure monitor **102** and/or pacemaker **114**" (col.15, lines 44-46). Information exchanged "may include not only pressure data, but pacing data, patient activity data, and other numbers, statistics or data". The programming of the pacemaker 114 may "reflect...the physician's judgment as to the pressure-based rate-responsive pacing appropriate for the patient".

In regard to claim 53, pacemaker **114** includes memory RAM **59** (Fig.5).

In regard to claim 57, pacemaker **114** is controlled by pressure monitor data (col.15, lines 14-18).

In regard to claim 61, the Struble system includes pacemaker leads **116** and **120** (Fig.6).

In regard to claim 62, the Struble system includes a defibrillator lead **124** (Fig.6).

In regard to claims 63 and 64, the leads of Struble carry "lead signal[s]" in the form of electrical ECG and pressure data signals.

In regard to claims 66 and 97, applicant's attention is directed to the electrodes/leads connected to sensor input amplifiers **37** and **43** (Fig.5). Any leads connecting to terminals **9,13** and **2,3** would inherently have to do both pacing and sensing of cardiac signals.

In regard to claim 88, the device of Struble can be used to treat CHF patients (col.1, lines 54-55; col.13, line 22; col.14, lines 24, 41-42).

In regard to claim 119, pacemaker **114** contains an antenna **56** (Fig.3) through which it communicates with RF telemetry **130** (Fig.6) and external input/output device **128**.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen (US 5,163,429) or Struble (US 6,580,946) in view of the textbook: The Founations of Cardiac Pacing, Pt.I: An Illustrated Practical Guide to Basic Pacing by Sutton et al, 1991.

Although the references of Cohen (US 5,163,429) and Struble (US 6,580,946) describe devices primarily as claimed by the applicant, neither reference specifically discloses the implantation of their devices near a patient's shoulder. The Sutton et al textbook: The Foundations of Cardiac Pacing, Pt.I: An Illustrated Practical Guide to Basic Pacing describes a procedure called "Subclavian Vein Puncture" (p.187) for inserting a pacemaker beneath a patient's skin in the area of the body just beside beneath the clavicle next to the shoulder (Fig.9). To have utilized this well known procedure for insertion of either the Cohen or Struble implants near a patient's shoulder would have been an obvious procedure to one of ordinary skill in the art of pacemaker implantation.

Allowable Subject Matter

18. Claims 5, 15, 89, 90, and 122-125 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

19. Claims 4, 6, 9, 12, 13, 19-23, 28, 29, 32-36, 38-40, 48, 51, 52, 54-56, 58, 67, 70-73, 76, 80, 81, 83-86, 94-96, 98-101, 120, and 121 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The Eigler et al (US 6,328,699) patent is cited for its pertinent disclosure of an implantable system having a pressure sensor in the patient's left atrium. Unlike applicant's claimed device, however, that of Eigler et al does not recite the generation of two electrical stimulation treatment signals.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (571) 272-4949. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Carl H. Layno

CARL LAYNO
PRIMARY EXAMINER

CHL
7/2/2007